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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/760,627	BROWN ET AL.					
Office Action Summary	Examiner	Art Unit	<del> </del>				
	Thomas R. Artman	2882					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence addi	ress				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim iill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this com D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on 17 Ja     2a)⊠ This action is FINAL. 2b)□ This     3)□ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		merits is				
Disposition of Claims		7					
4) ☐ Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-14 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.						
Application Papers							
9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 20 January 2004 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Ex	a)⊠ accepted or b)⊡ objected drawing(s) be held in abeyance. Section is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFF	R 1.121(d).				
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D  5) Notice of Informal F  6) Other:	ate	152)				

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes (US 6,721,386 B2) in view of Edic (US 6,353,653 B1) and Rasche (US 6,865,248 B1).

Regarding claims 1 and 8, Bulkes discloses a method and apparatus of CT scanning in which cardiac correlation techniques are applied to acquired projection images (col.5, lines 1-42).

Bulkes does not specifically disclose that the device performs cone beam CT scanning that provides 2-D projection images. Bulkes uses fan beam CT scanning, which requires different image reconstruction techniques. However, it is clear to one skilled in the art that the method of applying correlation techniques to select a particular set of projection data for reconstruction is independent of the type of reconstruction method. The method selects what projection images are to be reconstructed, not how to reconstruct them.

More specifically, Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, further taking into account the differences in

reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

Further regarding claims 1 and 8, Bulkes does not specifically disclose that the correlation techniques are respiratory correlation techniques. Bulkes discusses motion artifacts caused by cardiac cycles, not respiratory cycles. However, it is known to one skilled in the art that both cardiac and respiratory cycles cause image artifacts in reconstructed CT images, and therefore need to be correlated. Further, one skilled in the art would readily recognize that the method of Bulkes is equally applicable to correlating either or both cyclic physiological phenomena.

More specifically, Rasche teaches a CT scanning correlation technique for reducing cardiac motion artifacts, and further shows that the same correlation methods are useful for correlating respiratory motion (col.6, lines 22-52). This is particularly important in circumstances where the patient, whether due to age or physical condition, cannot hold their breath, which is a common mechanism that Bulkes relies upon in order to remove respiratory motion artifacts.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to correlate respiratory motion in order to reduce motion artifacts caused by the patient's respiratory cycle, as well as the cardiac cycle, as taught by Rasche.

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With respect to claims 2 and 9, the Bulkes/Rasche combination further teaches that the respiratory phase of the patient's motion is continuously monitored (col.5, lines 1-15 of Bulkes).

With respect to claims 3 and 10, Bulkes further discloses that the projection images that have comparable phases are selected from a complete data set upon completion of the acquisition of projection images and are used to reconstruct the volume data (col.5, lines 16-42).

Claims 4, 5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes, Edic and Rasche, as applied to claims 2 and 9, respectively, in view of Hsieh (US 6,480,560 B2).

With respect to claims 4 and 11, neither Bulkes nor Edic nor Rasche specifically disclose that the breathing phase is determined by a feature in the projection image.

Hsieh specifically teaches the practice of measuring the mechanics of a feature (in this case, the heart) through analysis of the projection images in order to determine the phase of the cyclic motion and then use the phase to correlate projection images of common phase (see at least Abstract and Fig.3). In this way, a more accurate phase is measured rather than through measurements from other monitors (similar to that of Bulkes and Rasche) without the need for any additional monitors (col.2, lines 1-8 and lines 39-44). A more accurate phase determination

allows for a more accurate reconstructed image due to improved correlation for selecting the projection data to reconstruct with respect to the phase of the motion.

Although Hsieh teaches the method specifically for determining the cardiac phase, it is clear from the teachings of Rasche that respiratory phase must also be considered. More specifically, the diaphragm, which is feature useful for determining the breathing phase, is monitored by Rasche.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to determine the patients' breathing phase from a feature in the projection image in order to improve the accuracy of the phase determination, which in turn improves the image quality since a more accurate phase allows more accurate selection of in-phase projections for reconstruction purposes, as taught by Hsieh.

With respect to claims 5 and 12, none of Bulkes, Edic, Rasche and Hsieh specifically disclose the practice of tracking the position of the diaphragm in projection images in order to determine the respiratory phase of the patient.

However, the teachings of Rasche and Bulkes specifically state that, in order to measure cardiac phase accurately, the motion of the heart must be monitored since that organ is the source of the motion.

Hsieh further teaches that the most accurate way to measure the actual cardiac phase is to derive the phase from projection images of the heart itself.

Rasche further teaches that, in order to measure a respiratory phase accurately, the motion of the diaphragm must be monitored since that organ is the source of the motion.

Therefore it follows from the above teachings that it would have been obvious to one of ordinary skill in the art at the time the invention was made for Bulkes to measure the respiratory phase directly through images of the diaphragm, since Rasche recognizes that the position of the diaphragm should be monitored in order to accurately measure a breathing phase, and Hsieh recognizes that a more accurate way to measure the phase of physiological motion is directly through projection images of the organ causing the motion.

Claims 1, 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche in view of Edic.

Regarding claims 1 and 8, Rasche discloses a method and apparatus of CT scanning in which respiration correlation techniques are applied to the acquired projection images (col.6, lines 22-52).

Rasche does not specifically disclose the use of cone beam CT, which results in 2-D projection images. Rasche appears to use fan beam CT scanning, which requires different image reconstruction techniques. However, it is clear to one skilled in the art that the method of applying correlation techniques to acquiring a particular set of projection data for reconstruction is independent of the type of reconstruction method. The method of Rasche selects when to take the projection images, not how to reconstruct them.

More specifically, Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, further taking into account the differences in reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam

CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

With respect tot claims 2 and 9, Rasche further discloses that the phase of the patient's breathing is monitored continuously during acquisition.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche and Edic, as applied against claims 2 and 9 above, respectfully, in view of Bulkes.

With respect to both claims, Rasche does not specifically disclose the practice of selecting projection images with common breathing phases from a complete data set after acquisition of the complete data set for reconstructing an image of the object of interest. Rasche performs the typical gating technique where the phases are monitored in order to instruct the CT scanner when to take projection images as a function of phase.

Bulkes teaches the practice of continuously monitoring the phase of a patient's motion while simultaneously taking a complete set of projection data such that any phase of the heart can be accurately imaged. This is because the projection data is time stamped with the phase information from the ECG and motion detection monitors, and the images can be selected by

common phase and reconstructed as desired (col.5, lines -42). Further, the accuracy of Bulkes method is improved over that of Rasche because the CT scanning adjustments to the measured respiratory cycle are not as accurate as being able to select time-stamped images after acquisition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to select projection images with common breathing phases from a complete set of data for a more accurate reconstruction of images of the object of interest as taught by Bulkes.

Claims 4, 5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche and Edic, as applied against claims 2 and 9 above, respectively, in view of Hsieh.

With respect to all the above claims, Rasche does not specifically disclose the practice of determining the breathing phase from a feature in the projection image, particularly that of the diaphragm.

Hsieh specifically teaches the practice of determining a cardiac phase by directly imaging the heart and deriving the phase from the heart in the projection images (col. col.2, lines 1-8 and lines 39-44). This is more accurate since it directly measures the heart's position rather than indirectly measuring the heart's motion through the ECG signals of Rasche, and thus does not require the additional equipment for such monitoring. A more accurate phase determination allows for a more accurate reconstructed image due to improved correlation for selecting the projection data to reconstruct with respect to the phase of the motion.

Hsieh does not, however, determine respiratory phase from images of the diaphragm.

Hsieh is concerned primarily with heart-induced motion artifacts and therefore determines the cardiac phase.

The teachings of Rasche specifically state that, in order to measure respiratory phase accurately, the motion of the diaphragm must be monitored since that organ is the source of the motion, just as the heart is the source of cardiac cycle induced motion (col.6, lines 22-52).

Therefore it follows from the above teachings that it would have been obvious to one of ordinary skill in the art at the time the invention was made for Rasche to measure the respiratory phase directly through images of the diaphragm, since Hsieh recognizes that a more accurate way to measure the phase of physiological motion is directly through projection images of the organ causing the motion.

Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bulkes, Edic and Rasche, as applied to claims 1 and 8 above, respectfully, in view of Mostafavi (US 6,937,696 B1).

With respect to both claims, neither Bulkes nor Edic and Rasche specifically disclose the practice of using visual or audible prompts provided for the patient's breathing. Bulkes merely states that the patient is instructed to carry out a series of breath-holds during the scanning procedure.

Mostafavi specifically teaches the practice of using audible and visual prompts for the patient's breathing (col.3, lines 29-44). This provides improved control over the position of the region of interest for more accurate imaging and positioning of the procedure system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use audible and/or visual prompts in order to improve the correlation with the image data and the patient's breathing cycle as taught by Mostafavi.

Claims 1, 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanematsu (US 6,385,288 B1) in view of Edic and Mostafavi.

Regarding claims 1 and 14, Kanematsu discloses a method and apparatus that applied respiratory correlation techniques to acquired projection images (col.3, lines 55-59; col.11, lines 35-58).

Kanematsu does not specifically disclose cone beam CT scanning. Kanematsu appears to use fan beam CT scanning, which requires different image reconstruction techniques.

Edic teaches a method of physiological gating to reduce motion artifacts in CT scanning where cone beam CT scanning can be used in lieu of fan beam scanning in order to further reduce motion artifacts, taking into account the differences in reconstruction methods as is known in the art (col.3, line 59, through col.4, line 9). Cone beam CT scanning takes a 2-D image, rather than the 1-D slice taken by fan beam CT scanning, and is therefore a faster scanning method for acquiring the necessary projection data over a given region of a patient. The speed helps to further reduce motion artifacts as well as reduce the total radiation dose to the patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to use cone beam CT scanning in order to image the patient more efficiently and safely as taught by Edic.

Further regarding claim 14 and with respect to claim 7, Kanematsu does not specifically disclose delivering the therapeutic radiation at times correlated with the patient's breathing cycle. Kanematsu uses the correlated image data to move the patient table with a constant therapeutic radiation beam.

Mostafavi teaches the practice of gating the therapeutic radiation in correlation with the breathing cycle of a patient (col.1, lines 50-67; col.2, lines 21-39). In this way, the therapeutic radiation is less likely to harm surrounding healthy tissue than risking the delay of moving the patient undergoing therapeutic radiation constantly to keep up with the respiration cycle.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to gate the therapeutic radiation in correlation with the patient's breathing cycle in order to more safely treat the patient, as generally taught by Mostafavi.

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# Response to Arguments

Applicant's arguments filed January 17<sup>th</sup>, 2006, have been fully considered but they are not persuasive. Applicants assert that the prior art of record, individually or combined, do not teach the claimed methods. The examiner respectfully disagrees.

First, the examiner wishes to point out that Applicants have raised many issues which simply do not exist in the claims. Applicants arguments delve into substantial detail regarding how the Applicants' correlation methods are different than the correlation methods of the prior art of record. However, none of those details are claimed. Neither independent claims 1 nor 8, specify a particular correlation method, and neither claim, particularly claim 1, specifies what acquired projection images are reconstructed, nor how they are to be reconstructed (aside from the limitation that cone-beam CT imaging is used). Only claims 3 and 10 define a particular respiration correlation technique, and only claims 2, 4, 5, 9, 11 and 12 define various aspects of how the respiratory phase is determined. At least for this reason, Applicants' arguments are not persuasive.

Second, it appears as though Applicants have misconstrued certain critical aspects of the above rejections. The examiner will now clarify the grounds of rejection. There are two general grounds of rejection, the first being based upon a combination of Bulkes in view of Edic and Rasche, and the second based upon Rasche in view of Edic, both of which are modified further by Hsieh. Each ground of rejection will now be reviewed in turn, starting with the combination of Bulkes in view of Edic and Rasche.

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Bulkes performs cardiac correlation techniques on acquired CT projection images. It doesn't matter what specific correlation technique is used, because independent claims 1 and 8 do not specify a particular correlation technique. The first deficiency of Bulkes, regarding claims 1 and 8, is that 1-D projection images are used since fan beam CT is used, not cone-beam CT. The role of Edic in all the rejections is largely for evidence to show that one skilled in the art would readily substitute cone beam CT for fan beam CT for the obvious advantage of greatly increasing acquisition time and reducing the total X-ray dose to the patient. The fact that Edic teaches this substitution in the context of cardiac correlation techniques provides strength to the rejection. This is because the substitution of cone beam CT is recognized in the field of physiologic cycle correlation of projection images. The specific manner in which the images of Edic are correlated is largely inconsequential to the rejection, is not relied upon in the rejection, and has little bearing on the obviousness of the combination.

The second, and more important deficiency of Bulkes regarding claims 1 and 8, is the fact that the correlation techniques disclosed are based upon the cardiac cycle, rather than the respiratory cycle. Here, Rasche discloses both cardiac and respiratory correlation techniques, either performed independently or combined, and the reasons why the respiratory cycle movement, as well as the cardiac cycle movement, must be considered for improved image quality. Columns 3 and 6 of Rasche are clear and specific on the need to consider the respiratory phase for accurate CT imaging as well as the methods by which the respiratory phase is monitored (abdominal belt and/or other sensor modalities for determining diaphragm motion) and the methods by which the images are correlated to the respiratory cycle. Again, since a specific respiration correlation technique is not required by the independent claims, then the

details of the correlation techniques of Rasche are inconsequential and not paramount to the *prima facie* case of obviousness. The only requirement is that the teachings of Rasche make it clear that respiration correlation is known in the prior art. This is all that is required by claims 1 and 8.

The next modification is in view of Hsieh regarding claims 4 and 11. Let it be noted here that intervening claims 2 and 9, respectively, do not add any further limitation to the very broad "respiration correlation techniques" limitation recited in the independent claims. The deficiency of the combination of Bulkes in view of Edic and Rasche regarding claims 4 and 11 is that the phases of the respiratory cycle are not determined through the use of a feature in the projection images. Hsieh specifically teaches the practice of using projection images of the heart in order to most accurately determine the phase of the heart. This now leads into a discussion of claims 5 and 12, which specifically require that the diaphragm is the feature to be used.

The modification of Bulkes with the teachings of Rasche in the independent claims has already established the obviousness of the practice and need of correlating the respiratory cycle in CT imaging, and further through monitoring of the diaphragm (via the abdominal belt of Rasche). Hsieh specifically teaches a more accurate method of determining the cardiac phase of a patient by using projection images of the heart, since the heart is the source of the motion caused by the cardiac cycle. Therefore, it simply follows to one of ordinary skill in the art that a more accurate determination of the respiratory phase should be based upon projection images of the diaphragm, since the diaphragm is the source of motion caused by the respiratory cycle. This

is particularly poignant considering that Rasche teaches the practice of measuring the movement of the diaphragm in order to determine the respiratory phase.

Applicants arguments, starting on p.10 of the Response, state specifically how Hsieh performs the determination of phase and how the specifics of Applicants' invention are different. Whether or not this is true is irrelevant because such details are not claimed. Hsieh provides the teaching of the practice and significance of using the CT images only, rather than other extrasensory devices such as the various sensors of Bulkes and Rasche, in order to determine the cardiac phase more precisely. This is sufficient for a *prima facie* case of obviousness against the invention as claimed.

We now turn to the second major ground of rejection, Rasche in view of Edic. Here, the explanation is rather straightforward since Rasche specifically discloses respiratory correlation techniques being applied to CT projection images. Again, the specific manner in which correlation is performed is irrelevant since the independent claims are not specific. As long as any sort of "correlation" of the projection images based upon the respiratory cycle is being performed, then this portion of the independent claims is anticipated. The deficiency of Rasche here is the fact that the specific type of CT imaging is not disclosed, either fan-beam or cone beam CT. Therefore, as discussed above and will not be elaborated here, Edic provides evidence to the fact that the substitution of one for the other is known, and more particularly, in the field of physiological correlation of images for faster imaging and reduced radiation exposure to the patient.

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Next, the combination of Rasche in view of Edic is modified by Bulkes regarding claims 3 and 10. The deficiency of Rasche in view of Edic here is the practice of selecting projection images having the same phase from a set of projection images for reconstruction. Rasche teaches source gating, so there is no teaching of the selection of images of common phase from a set, since no images out of a given phase are acquired. Edic teaches interpolation of images from a set of images that are taken at various times throughout the cardiac cycle, and then selects a set of interpolated images based upon common phase. This is nearly identical to the claimed invention except that the images used for reconstruction were not acquired; the images are interpolated from acquired images.

Bulkes teaches the acquisition of a set of projection images, time-stamped with phase data from other monitors, such that individual images from a common phase can be selected for reconstruction. This provides an advantage over Rasche in that the source gating is less accurate and limited in imaging views compared to the method of Bulkes regarding correlated image acquisition. This also provides an advantage over Edic since the interpolation of images invariably leads to errors, where the method of Bulkes uses real acquired images.

Finally, the additional modification of Rasche in view of Edic and Bulkes by Hsieh for claims 4, 5, 11 and 12 are essentially the same here as with the first major combination of references. Since the same four references and teachings are present, the same arguments apply. Though the use of images of the diaphragm for respiratory phase determination are not specifically disclosed in either of the references, the disclosure of the main reference Rasche teaches monitoring the diaphragm, and Hsieh teaches the advantage of monitoring the images of

the organ responsible for the motion in order to more accurately determine the phase of the motion caused by the organ.

Regarding the remaining grounds, similar arguments apply. The independent claims 1, 8 and 14 are not specific, nor do they even require, a particular method of respiration correlation to a set of CT images. Therefore, since the combination of the prior art of record disclose the practice of "correlating" images to respiratory phases with proper motivation regarding why it is important, then the *prima facie* case of obviousness has been made.

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### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Erbel (US 6,898,456 B2) teaches the practice of adjusting radiation therapy to imaged positions of tumors that are moving as a result of the respiratory cycle. Cesmeli (US 6,434,215 B1) teaches the practice of imaging a beating heart.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas R. Artman whose telephone number is (571) 272-2485. The examiner can normally be reached on 9am - 5:30pm Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas R. Artman Patent Examiner

EDWAND & GLICK
SUPERVISORY PATENT EXAMINER